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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,399	12/21/2001	Brian J. Martinell	MONS:132US	2956
73905 7590 04/22/2008 SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 SOUTH WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606				
			EXAMINER WORLEY, CATHY KINGDON	
			ART UNIT 1638	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/683,399

Applicant(s)

MARTINELL ET AL.

Examiner

CATHY K. WORLEY

Art Unit

1638

Period for Reply -- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 22, and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed Dec. 26, 2007, has been entered.
2. Claims 20 and 21 have been cancelled.
Claims 22 and 23 have been added.
Claims 1-19, 22, and 23 are pending and are examined in the present office action.
3. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Rejections - 35 USC § 103

4. Claims 1-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Martinell et al (US Patent No. 5,914,451, issued on June 22, 1999) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907) for the reasons of record stated in the previous Office Action mailed on Aug. 22, 2007. The Applicants arguments in the response filed on Dec. 26, 2007, have been fully considered but were not found to be persuasive.

The Applicant argues that neither Martinell et al nor Jefferson et al teach or suggest assaying roots to determine whether a plant is germline transformed (see paragraph bridging pages 5-6 of the response filed on Dec. 26, 2007). This is not persuasive, however, because the applicant's own data demonstrate that there is only a 70% or 74% correlation between root assay positives and germline positives (see Table 4, bridging pages 20-21 of the specification). Therefore, assaying roots is not a true determination of a germline transformation, it is merely an indicator. Furthermore, the prior art teaches the same materials and method steps, therefore, a difference in the intended use does not distinguish the instant claims over the prior art.

The Applicant argues that the instant invention provides unexpected results and a solution to a long felt need (see page 6 of the response filed on Dec. 26, 2007). They argue that roots provide a superior indicator of germline transformation over other tissues (see page 6 of the response). This is not persuasive, however, because they have not provided data to demonstrate this assertion. The data provided compare growth on selectable media vs. root assays and the correlation between these two indicators and germline positives. Table 4 indicates either 70% or 74% correlation between root assay positives and germline positives (see Table 4, bridging pages 20-21 of the specification). Table 3 indicates either 81% or 84% correlation between growing putative transformants on selectable media and

germline positives (see Table 3, page 20 of the specification). There are no data comparing root assays vs. assays from other tissues.

The Applicant provides arguments regarding plants that were grown under either glyphosate or kanamycin selection, subsequently removed from the selection, rooted in the absence of a selection agent, and subsequently performed root assays (see pages 6-8 of the response filed on Dec. 26, 2007). These arguments and these data are not persuasive, because none of the claims recite a method with these particular steps. There are no claims that recite first growing with selection, then removing the positives from selection to grow roots, then assaying the roots for the enzymatic activity of the selectable marker. Therefore, the arguments do not apply to any of the instant claims.

5. Claims 1-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Firoozabady et al (PMB (1987) Vol. 10, pp. 105-116) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907) for the reasons of record stated in the previous Office Action mailed on Aug. 22, 2007. The Applicant's arguments in the response filed on Dec. 26, 2007, have been fully considered but were not found to be persuasive..

The Applicant argues that neither Firoozabady et al nor Jefferson et al teach or suggest assaying roots to determine whether a plant is germline transformed (see third paragraph on page 9 of the response filed on Dec. 26, 2007). This is not

persuasive, however, because the applicant's own data demonstrate that there is only a 70% or 74% correlation between root assay positives and germline positives (see Table 4, bridging pages 20-21 of the specification). Therefore, assaying roots is not a true determination of a germline transformation, it is merely an indicator. Furthermore, the prior art teaches the same materials and method steps, therefore, a difference in the intended use does not distinguish the instant claims over the prior art.

The Applicant argues that the instant invention provides unexpected results and a solution to a long felt need (see paragraph bridging pages 9-10 of the response filed on Dec. 26, 2007). They argue that roots provide a superior indicator of germline transformation over other tissues (see second paragraph on page 10 of the response). This is not persuasive, however, because they have not provided data to demonstrate this assertion. The data provided compare growth on selectable media vs. root assays and the correlation between these two indicators and germline positives. Table 4 indicates either 70% or 74% correlation between root assay positives and germline positives (see Table 4, bridging pages 20-21 of the specification). Table 3 indicates either 81% or 84% correlation between growing putative transformants on selectable media and germline positives (see Table 3, page 20 of the specification). There are no data comparing root assays vs. assays from other tissues.

6. New Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinell et al (US Patent No. 5,914,451, issued on June 22, 1999) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907) as applied to claims 1-19, above, and further in view of Valvekens et al (PNAS (1998) Vol. 85, pp. 5536-5540)

The new claims are drawn to a method for early identification of germline transformed plants. The elements recited in the claims are:

- 1) transforming meristemic or cotyledonary tissue with a plant expressible construct
- 2) expressible construct comprises two nucleic acids each encoding a protein
- 3) expressible construct comprises a selectable marker (claim 4)
- 4) producing a shoot
- 5) growing roots from the shoot
- 6) obtaining an extract of transformed root tissue
- 7) assaying the root extract for the presence of the nucleic acid sequence
- 8) identifying roots that assay positive
- 9) the roots are grown in the absence of a selection agent
- 10) the selection agent is glyphosate (for claim 23).

None of these elements are novel (see below for an item-by-item account of references from the prior art that teach these elements), and there is no indication of a particular element that is critical. In the absence of any evidence of criticality

or unexpected results, any combination of these elements is an obvious variant of methods that are taught in the prior art. To demonstrate the obviousness of the claimed invention, the Examiner will analyze the fact patterns according to *Graham v. Deere* analysis.

SCOPE AND CONTENT OF THE PRIOR ART – PRIMARY REFERENCE

In the prior art, Martinell et al teach many of the limitations recited in the instant claims. They teach the transformation of soybeans (see entire document). They teach the use of meristematic tissue for transformation (see column 8, lines 15-45). They teach culturing the transformed tissue to produce shoots (see column 8, lines 59-67). They teach culturing the transformed shoots on bean rooting medium to induce the growth of roots (see column 9, lines 1-17). They teach the use of the EPSP gene which confers resistance to glyphosate and they teach the use of glyphosate as a selectable marker (see column 9, lines 1-5; and column 5, lines 25-41).

They teach that genetically engineered soybeans can have advantageous qualities: such as higher yields, pest resistance, enhanced nutritional value, and improved storage qualities, which are traits that can be conferred to a soybean by transformation with a plant expressible construct (see column 3, lines 4-11). They teach a plasmid encoding the EPSP gene (referred to as CP4) as well as encoding β -

glucuronidase (GUS) (see column 9, Table 1, and lines 46-58); therefore the plant expressible construct taught by Martinell et al comprised two nucleic acid sequence each encoding a protein. They screened for the presence of the protein encoded by the CP4 gene by ELISA (see paragraph bridging columns 9-10).

DIFFERENCES BETWEEN THE CLAIMED INVENTION AND THE PRIOR ART

Martinell et al do not teach obtaining an extract of root tissue from the transformed plant tissue and assaying the extract for the presence of the nucleic acid sequence. They do not teach growing roots in the absence of a selection agent.

SCOPE AND CONTENT OF THE PRIOR ART – SECONDARY REFERENCE

In the prior art, Jefferson et al teach obtaining an extract of root tissue from transformed plants and assaying for reporter activity which indicated the presence of the nucleic acid sequence (see page 3903, Figure 2). They do not teach growing roots in the absence of a selection agent.

SCOPE AND CONTENT OF THE PRIOR ART – TERTIARY REFERENCE

Valvekens et al teach that shoots from transformed calli are transferred to a rooting medium that contains only GM media (see left column on page 5537); therefore this is in the absence of a selection agent. Valvekens teach two selectable markers and enzymatic assays for these markers (see left column on page 5537).

LEVEL OF ORDINARY SKILL IN THE PERTINANT ART

One of ordinary skill in the pertinent art would have had a Ph.D. degree in molecular biology, plant biology, or some other biological science that emphasizes genetic engineering in plant systems. One of ordinary skill in this art would have been well-read in methods of plant transformation and would have been aware of different methods for transferring nucleic acids into host cells, different selectable markers, different tissues from different plant species, methods for generating shoots and roots and for regenerating whole plants from transformed tissue, and methods of assaying for the presence of the transgene in the resulting transformants. One of ordinary skill in this art would have appreciated that each plant species would have required some routine experimentation to optimize the efficiency of transformation and would have appreciated that different combinations of elements that are known in the art could have been combined to produce an efficient transformation method. This skill level is evidenced by the skill of Martinell, Jefferson, Valvekens and their co-authors.

COMBINING PRIOR ART ELEMENTS TO YIELD PREDICTABLE RESULTS

The prior art references relied on teach each element claimed. Therefore, all elements of the instant invention were known in the art prior to the filing of the instant application.

One of ordinary skill in the art could have combined the elements as claimed, and each of the elements would have performed their known functions.

One of ordinary skill in the art would have predicted that the result would be a reasonably efficient method of transformation for plants. Therefore, the results achieved by the instant invention are not unexpected.

Double Patenting

7. Claims 1-19 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5-8, and 10-12 of U.S. Patent No. 5,914,451 (Martinell et al, issued on June 22, 1999, assignee: Monsanto Company) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907) for the reasons of record stated in the previous Office Action mailed on Aug. 22, 2007. The Applicant did not provide any arguments to refute this rejection and has stated that a Terminal Disclaimer will be submitted upon the allowability of the case (see third paragraph on page 10 of the response filed on Dec. 26, 2007).

8. New claims 22 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5-8, and 10-12 of U.S. Patent No. 5,914,451 (Martinell et al, issued on June 22, 1999, assignee: Monsanto Company) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907) and further in view of Valvekens et al (PNAS (1988) Vol. 85, pp. 5536-5540).

The claims are drawn to a method for early identification of germline transformed plants wherein the roots are grown in the absence of a selection agent, and wherein the selection agent is glyphosate.

None of the elements recited in the claims are novel (see below for an item-by-item account of references from the prior art that teach these elements), and there is no indication of a particular element that is critical. In the absence of any evidence of criticality or unexpected results, any combination of these elements is an obvious variant of methods taught and claimed by Martinell et al modified to include elements taught by Jefferson et al and Valvekens et al.

In the previous patent, Martinell et al teach many of the limitations recited in the instant claims. They teach the transformation of soybeans (see entire document). They teach the use of meristematic tissue for transformation (see column 8, lines 15-45). They teach culturing the transformed tissue to produce shoots (see column 8, lines 59-67). They teach culturing the transformed shoots on

bean rooting medium to induce the growth of roots (see column 9, lines 1-17). They teach the use of the EPSP gene which confers resistance to glyphosate and they teach the use of glyphosate as a selectable marker (see column 9, lines 1-5; and column 5, lines 25-41).

They teach that genetically engineered soybeans can have advantageous qualities: such as higher yields, pest resistance, enhanced nutritional value, and improved storage qualities, which are traits that can be conferred to a soybean by transformation with a plant expressible construct (see column 3, lines 4-11). They teach a plasmid encoding the EPSP gene (referred to as CP4) as well as encoding β -glucuronidase (GUS) (see column 9, Table 1, and lines 46-58); therefore the plant expressible construct taught by Martinell et al comprised two nucleic acid sequence each encoding a protein. They screened for the presence of the protein encoded by the CP4 gene by ELISA (see paragraph bridging columns 9-10).

Martinell et al do not teach obtaining an extract of root tissue from the transformed plant tissue and assaying the extract for the presence of the nucleic acid sequence. They do not teach growing roots in the absence of a selection agent.

In the prior art, Jefferson et al teach obtaining an extract of root tissue from transformed plants and assaying for reporter activity that indicated the presence of the nucleic acid sequence (see page 3903, Figure 2).

Valvekens et al teach that shoots from transformed calli are transferred to a rooting medium that contains only GM media (see left column on page 5537);

therefore this is in the absence of a selection agent. Valvekens teach two selectable markers and enzymatic assays for these markers (see left column on page 5537).

The prior art references relied on teach each element claimed, therefore, all elements of the instant invention were known in the art prior to the filing of the instant application.

One of ordinary skill in the art could have combined the elements as claimed, and each of the elements would have performed their known functions.

One of ordinary skill in the art would have predicted that the result would be a reasonably efficient method of transformation for plants. Therefore, the results achieved by the instant invention are not unexpected.

The prior art teaches assaying extracts from roots for the presence of a transgene. The prior art teaches transferring transformed shoots to selection-free media to grow roots (see Valvekens, left column on page 5537). In the absence of any evidence that assaying extracts from roots is a critical step that provides an unexpected result, the claimed method is merely an obvious variant of methods claimed by and taught in Martinell et al (US Patent No. 5,914,451) that utilize elements already known in the prior art. Therefore, claims 22 and 23 are unpatentable over Martinell et al in view of Jefferson et al and further in view of Valvekens et al under the judicially created doctrine for non-statutory double patenting.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Medina A Ibrahim/
Primary Examiner, Art Unit
1638

/CKW/